(e) ''Correction or removal report number'' means the number that uniquely identifies each report submitted.

(f) ''Distributor'' means any person, including any person who imports a device into the United States, who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.

(g) ''Manufacturer'' means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user or consumer;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.

(h) ''Market withdrawal'' means a correction or removal of a distributed device that involves a minor violation of the act that would not be subject to legal action by FDA or that involves no violation of the act, e.g., normal stock rotation practices.

(i) ''Removal'' means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

(j) ''Risk to health'' means

(1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or

(2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

(k) ''Routine servicing'' means any regularly scheduled maintenance of a device, including the replacement of parts at the end of their normal life expectancy, e.g., calibration, replacement of batteries, and responses to normal wear and tear. Repairs of an unexpected nature, replacement of parts earlier than their normal life expectancy, or identical repairs or replacements of multiple units of a device are not routine servicing.

(l) ''Stock recovery'' means the correction or removal of a device that has not been marketed or that has not left the direct control of the manufacturer, i.e., the device is located on the premises owned, or under the control of, the manufacturer, and no portion of the lot, model, code, or other relevant unit involved in the corrective or removal action has been released for sale or use.

Subpart B—Reports and Records

§ 806.10 Reports of corrections and removals.

(a) Each device manufacturer, importer, or distributor shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or distributor if the correction or removal was initiated:

(1) To reduce a risk to health posed by the device; or

(2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under § 806.1(b).

(b) The manufacturer, importer, or distributor shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal. The report shall be submitted to the appropriate FDA district office listed in § 5.115 of this chapter. A foreign manufacturer or owner or operator of devices must submit reports of corrective or removal actions.

(c) The manufacturer, importer, or distributor shall include the following information in the report:

(1) The seven digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation ''C'' or ''R''. For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567–6/1/97–001–C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567–7/1/97–002–C etc. For removals, the number will appear as follows: 1234567–6/1/97–001–R and 1234567–7/1/97–002–R, etc. Firms that do not have a seven digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000–6/1/97–001–C for corrections and 0000000–7/1/97–001–R for removals). Reports received without a seven digit registration number will be assigned a seven digit central file number by the district office reviewing the reports.

(2) The name, address, and telephone number of the manufacturer, importer, or distributor and the name, title, address, and telephone number of the manufacturer, importer, or distributor's representative responsible for conducting the device correction or removal.

(3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device.

(4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a preamendments device, and the device listing number. A manufacturer, importer, or distributor that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA.

(5) The model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

(6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report.

(7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken.

(8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers.

(9) The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal.

(10) The date of manufacture or distribution and the device's expiration date or expected life.

(11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee.

(12) A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section.

(13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted.

(d) If, after submitting a report under this part, a manufacturer, distributor, or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer, distributor, or importer shall within 10-working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer, distributor, or importer shall also provide a statement in accordance with paragraph (c)(13) of

this section for any required information that is not readily available.

(e) A report submitted by a manufacturer, distributor, or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, distributor, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer, distributor, or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury.

(f) No report of a correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803, 804, or 1004 of this chapter.

EFFECTIVE DATE NOTE: At 62 FR 67274, Dec. 24, 1997, §806.10 was stayed. This section contains information collection requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 806.20 Records of corrections and removals not required to be reported.

(a) Each device manufacturer, importer, or distributor who initiates a correction or removal of a device that is not required to be reported to FDA under §806.10 shall keep a record of such correction or removal.

(b) Records of corrections and removals not required to be reported to FDA under §806.10 shall contain the following information:

(1) The brand name, common or usual name, classification, name and product code if known, and the intended use of the device.

(2) The model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

(3) A description of the event(s) giving rise to the information reported and the corrective or removal action that has been, and is expected to be taken.

(4) Justification for not reporting the correction or removal action to FDA, which shall contain conclusions and any followups, and be reviewed and evaluated by a designated person.

(5) A copy of all communications regarding the correction or removal.

(c) The manufacturer, importer, or distributor shall retain all records required under this section for a period of 2 years beyond the expected life of the device, even if the manufacturer, importer, or distributor has ceased to manufacture, import, or distribute the device. Records required to be maintained under paragraph (b) of this section must be transferred to the new manufacturer, importer, or distributor of the device and maintained for the required period of time.

EFFECTIVE DATE NOTE: At 62 FR 67274, Dec. 24, 1997, §806.20 was stayed. This section contains information collection requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 806.30 FDA access to records.

Each device manufacturer, importer, or distributor required under this part to maintain records concerning corrections or removals and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by FDA and under section 704(e) of the act, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records and reports.

§ 806.40 Public availability of reports.

(a) Any report submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under §20.61 of this chapter; and

(2) Any personnel, medical, or similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under §20.63 of this chapter or 5 U.S.C. 552(b)(6); provided, that except for the information under §20.61 of this chapter or 5 U.S.C. 552(b)(4), FDA will disclose to a patient